

05-SMO-015	VALIDATION OF PROCEDURES FOR MONITORING CREWMEMBER IMMUNE FUNCTION	Integrated Immune
Principal Investigator		
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Description		
<p>The objective of this Supplemental Medical Objective (SMO) is to develop and validate an immune monitoring strategy consistent with operational flight requirements and constraints. There are no procedures currently in place to monitor immune function or its influence on crew health. Immune dysregulation has been demonstrated to occur during spaceflight. This may be a result of microgravity, confinement, physiological stress, radiation, environment or other mission-associated factors. The clinical risk from prolonged immune dysfunction is unknown. This SMO assesses the clinical risks resulting from the adverse effects of space flight on the human immune system and will validate a flight-compatible immune monitoring strategy. Identification and characterization of the clinical risk and the development of a monitoring strategy are necessary prerequisite activities prior to validating countermeasures. There is evidence to suggest that space flight leads to laboratory evidence of immune system dysregulation. In order to develop the best monitoring strategy that can successfully be implemented within the spacecraft flight constraints, we have examined terrestrial analogues, clinical medicine, and previous space flight experience. This review was distilled to select appropriate immune markers for routine monitoring of crewmember immune function. Pre-flight, in-flight and post-flight assessments will be performed. The in-flight samples will allow a distinction between real in-flight alterations and the physiological stresses of landing which are believed to alter landing day assessments. The overall status of the immune system during flight (activation, deficiency, dysregulation) and the response of the immune system to specific latent virus reactivation (known to occur during space flight) will be assessed. Following completion of the SMO, the data will be evaluated to determine the optimal set of assays for routine monitoring of crewmember immune system function. It is intended that the determined set of relevant assays will be used to document clinically relevant findings and monitor the effectiveness of human medical countermeasures. In addition, the validated assays will have significant benefit for the routine monitoring of crewmembers' immune system status with regards to diagnosis and prognosis of immune-related disease states. Very little hard data exists regarding in-flight adverse medical events and the body's ability to recover from such events during spaceflight. Of particular concern are conditions related to immunology, such as allergies, rashes, hypersensitivities, infections and wound healing. The data that does exist is often sequestered due to medical confidentiality. So in addition to collecting blood, saliva and urine crewmembers will be requested to complete an immunology health survey. The purpose of this survey is to periodically record crewmembers' experiences and impressions (wound healing in particular) regarding these adverse medical events. The survey will be completed pre, in- and post-flight.</p>		
Objectives		
<p>Examine the detectable immune system changes associated with the in-flight period, distinct from post-landing assessments. Specifically, this study will determine the scope of clinical changes associated with spaceflight by assessing: leukocyte subset distribution; cytokine profile changes [Ribonucleic Acid (RNA), intracellular, secreted), viral reactivation (viral specific T cell number/function, viral antibody levels, viral Deoxyribonucleic Acid (DNA) detection], and physiological stress hormone levels.</p>		
Relevance		
<p>Immune dysfunction has been demonstrated to occur during spaceflight, and in certain ground-based models of spaceflight. Immune dysregulation, in conjunction with high energy radiation exposure and latent viral reactivation, may have important health consequences during exploration class space flights. The assays developed and validated during the execution of the Integrated Immune SMO will likely be found appropriate for the monitoring of space-related immune alterations. Although true clinical immunology remains immature (with the CD4 count the primary exception), these assays may have potential terrestrial applications for the monitoring of immune function in terrestrial populations with altered immunity (ranging from high stress individuals to remote field applications).</p>		
BDC Summary		
<p>Blood, 24-hr. urine and two types of saliva samples (liquid and dry book) will be collected preflight and postflight for all subjects. The pre-flight sessions occur on L-180 and L-45 and the post-flight sessions on R+0 to R+30. For each BDC session, there is a single blood draw, single dry-saliva collection, single 24-hr urine collection, and four liquid saliva collections (performed every other day for 7 days and centered around the blood collection day). The 24 hr. void-by-void urine collection starts with the first void on the day of the blood draw and concludes with the first void of the following day. Whenever possible, BDC sessions will coincide with Medical Operations collections.</p>		
In-flight Operations Summary		

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Three sessions are performed in-flight: early, mid and late increment. Each session consists of four liquid saliva collections (performed every other day), with a blood draw and dry book saliva sample collection occurring on the last day of the liquid saliva collections. For the late increment session, the final liquid saliva sample, the blood draw and dry book saliva sample collection occur on R-1. There is no inflight urine collection. A photo session will be performed if time allows (currently carried as reserve activity).		